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09/607,240	06/30/2000	Matthew Joseph Doyle	8147	8182

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EXAMINER
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DECLoux, AMY M

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 13

Application Number: 09/607,240  
Filing Date: June 30, 2000  
Appellant(s): DOYLE ET AL.

**MAILED**  
**JUN 03 2003**  
**GROUP 2900**

\_\_\_\_\_  
Emelyn L. Hiland  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3-21-03.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

No amendment after final has been filed.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with. In Section VII of the Brief entitled "Grouping of Claims", Appellant groups claims 5, 6 and 8 together, and also states that claims 7 and 9 stand or fall together. The examiner notes that Appellant does not specifically state that claims 5, 6 and 8, and claims 7 and 9 do or do not stand or fall together. The Examiner notes that claims 5-9 must all stand or fall together because dependent claims 7 and 9 are stated by Appellant to stand or fall together, and they are

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dependent on independent claims 5 and 8, respectively, which Appellant has grouped together with Claim 6. Therefore, it follows that claims 5-9 stand or fall together.

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

US 5,364,616

Singer et al.

11-1994

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al (U.S. No. 5,364,616).

'616 teaches a method for treatment and prevention of the oral cavity diseases of gingivitis or periodontitis comprising the topical administration of the oral cavity of a composition comprising an antimicrobial anti-plaque agent (including numerous agents instantly recited in claims 1-2 and 8), and a histamine-2 receptor antagonist compound (including many agents instantly recited in claim 4) and a pharmaceutically acceptable oral carrier (see entire patent especially the abstract and claims 9-10, 16, 19 and 23, and column 21, lines 5-18, column 18, line 48 and column 19, line 7). '616 further teaches that said oral carrier contains components that are suitable for administration to the oral cavity of a human or lower animal (see entire patent especially column 25, lines 36-40). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V.

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Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01)).

Therefore, the referenced teachings anticipate the claimed invention.

**(11) *Response to Argument***

As stated on page 4 of the Brief, Appellants states that it is the position of the Examiner that Appellant has discovered a new benefit (whole body health) of an old process (topical administration to the oral cavity of an antimicrobial agent optionally with an H2 antagonist) and that the Examiner contends that “in the instant claims there is no new use of a known product”.

Appellant contends the rejection is improper because the process taught by Singer et al does not disclose all the material elements of the claims, specifically the limitation of promoting whole body or systemic health, and the limitation that such systemic benefit would be provided by topically administering the present antimicrobial compositions. However, the Examiner contends that the process taught by Singer would inherently promote whole body health or systemic benefits because the compositions taught by Singer are identical to that claimed, both in terms of the ingredients comprised by said compositions, and in terms of the concentration of said ingredients in said compositions, and also because the route of administration (oral topical) of the compositions taught by Singer is identical to that claimed.

Appellant contends that the only use disclosed by Singer et al for the compositions which contain the H2-antagonist and an antimicrobial antiplaque agent, is for treatment of gingivitis, periodontitis and dental plaque, and that the instantly claimed methods are based on the discovery that topical administration of selected antimicrobial agents affords unanticipated benefits of preventing entry into the systemic circulation of oral pathogens and their products, which are believed to prompt the systemic inflammatory mechanisms and complications that contribute to systemic diseases and disorders. The Examiner acknowledges that although Singer does not specifically teach the systemic benefits of the instantly claimed methods, said claimed systemic benefits would be inherent by virtue of the antimicrobial mechanism of action of said compositions. Accordingly, said systemic benefits are an extension of the method of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by Singer et al. Said antimicrobial action of said compositions effects a decrease in oral pathogens in the oral cavity, thereby resulting in reduced entry into the systemic circulation of oral pathogens and their products, which are believed to prompt the systemic inflammatory mechanisms and complications that contribute to systemic diseases and disorders.

Appellant contends on page 5 of the Brief that the present case is different from *Bristol* because the present "use", namely "promoting whole body health" is not known nor suggested by the art, while the "use" in *Bristol*, ie "treating cancer by administering paclitaxel" is the same use as disclosed in the prior art ie that of treating cancer. However, the examiner notes that the claimed method of "promoting whole body health" in the instant case is an extension of the method taught by Singer et al because the claimed method of promotion of whole body health is a direct result of the antimicrobial effect on oral pathogens mediated by administration of a

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composition comprising the same ingredients, in the same concentrations, and administered by the same route as that taught by Singer et al.

Appellant further contends on page 6 of the Brief that the present case is different from the *In re Woodruff* because the claimed method was directed to the same use and not to a new use or purpose. In *In re Woodruff* the claimed use to inhibit the visible growth of fungi on refrigerated fruits and vegetables was found to be generically encompassed by the prior art which is directed to a method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature in order to maintain a fresh appearance. Appellant states that Woodruff's method is therefore not directed to a new use or purpose, but simply a more specific benefit of inhibiting the visible growth of fungi. However, the Examiner notes that if Woodruff's method of inhibiting the growth of fungi is considered to be directed to the same use as the method of the prior art which is directed to a method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature, and is not directed to a new use or purpose, then Woodruff's method is thus a result or extension of the prior art's method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature, because the method of the prior art is also mediated by inhibiting the visible growth of fungi. Similarly, the systemic benefits of the instantly claimed methods of promoting whole body health is not directed to a new use over the method of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by Singer et al. because said claimed systemic benefits are mediated by the antimicrobial mechanism of action of said compositions and thus the instantly claimed method of promoting whole body health is a result or extension of the prior art's method of

treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by Singer et al.

Appellant further contends on page 6 of the Brief that the present case is different from the *Verdegaal Bros., Inc v Union Oil* because the claimed method was directed to the same use and not to a new use or purpose. However as stated in the previous paragraph, it is the Examiner's position that the systemic benefits of the instantly claimed methods are an extension of the method of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by Singer et al. for the reasons discussed supra.

Appellant further contends on page 7 of the Brief that the present case is different from the *Bird Provision Co v Owens Country Sausage, Inc* because the claimed use in Bird is not a new use, and that though the public did not understand or appreciate the shelf life implications of the process of producing and preserving fresh pork sausage. Similarly, the Examiner contends that the instant claims encompass a use that was inherent to the methods taught by Singer et al, despite the lack of appreciation of the systemic effects of the known process of treatment of the localized oral disorders of gingivitis, periodontitis and dental plaque taught by Singer et al.

Appellant further contends on page 7 of the Brief that the present claimed methods involving topically administering a composition comprising an antimicrobial agent and an H2-antagonist has new and unobvious beneficial effects and are therefore patentable as a new use of a process even if the process were known. In support of said position, Appellant presents on page 8 of said brief that in *In re Shetty* the CCPA reversed an obviousness rejection. However the Examiner notes that the present rejection is a 102 art rejection, not a 103 obviousness rejection, and as such does not apply instantly. Also in support of said position, Appellant



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presents on pages 8-9 of the Brief that in *In re Marshall* claims directed to a method of controlling weight using oxethazaine was not anticipated by art which taught that oxethazain was used to treat digestive diseases such as esophagitis, gastritis. The Examiner notes that in *Marshall* the method of controlling weight was not a direct result or extension of the successful treatment of digestive disease. However, unlike *Marshall*, the method encompassed by the instantly recited claims is an extension of the methods taught by Singer et al mediated by the local antimicrobial mechanism which confers the claimed systemic effects of whole body health, and as such is not an accidental or unwitting duplication of an invention which the CCPA stated can not constitute an anticipation.

Appellants further contend on page 9 of the Brief that the Examiner has not provided evidence that one of ordinary skill in the art would recognize the new use of the present claimed method, i.e. promoting systemic or whole body health. However, the examiner notes that one of ordinary skill in the art would recognize that the method of Singer et al would reduce the quantity of oral pathogens in the oral cavity, and that this in turn would reduce the quantity of pathogens entering the bloodstream from the gums. The examiner notes that one of ordinary skill in the art would recognize that reduction of said pathogens in the blood would promote systemic or whole body health.

Appellants further contend on pages 9-10 of the Brief, that a second or new medicinal use of a substance is patentable as a method of use. Appellant cites US Patent 6,100,270, which involves the oral administration of sildenafil compositions for a second medicinal use, though said compositions had been previously patented for the treatment of various other conditions. However, the Examiner notes that the dosages of the substance administered for each of the

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conditions was not identical in the various patents. Appellant also cites that methods of treating male pattern baldness by the topical administration of minoxidil were patented as a second medicinal use, and that a previous patented use was for a method of treating hypertension. However, the Examiner notes that the method of treating male pattern baldness by the topical administration of minoxidil is not a direct extension of the method of treating hypertension because of their divergent mechanisms of action in different patient populations, and is therefore not analogous to the instant application.

On page 10 of the Brief, Appellant disagrees with the Examiner's contention that, unlike the present case in which the claimed methods are applied to the same patient population, the methods in the cases of patented second medicinal uses are applied to various distinct patient populations. Appellant states that the present claimed methods are for use in all subjects, regardless of their need for treatment of dental plaque, gingivitis or periodontitis. However the Examiner notes that the methods claimed by Singer et al are not limited to subjects with need for treatment of dental plaque, gingivitis or periodontitis, because Claim 1 of Singer et al recites a method of preventing of dental plaque, gingivitis or periodontitis, which would apply for all subjects.

Accordingly, it is the position of the Examiner that though Appellant is claiming a new benefit (whole body health) of an old process (topical administration to the oral cavity of an antimicrobial agent optionally with an H2 antagonist), the method of promoting whole body health defined by instant Claims 5-9 is not patentably distinct from Singer et al. for the reasons discussed above, Therefore the rejection of instant claims 5-9 under 102(b) as being anticipated by Singer et al. is proper.

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For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,


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Patent Examiner  
June 1, 2003

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